

EXHIBIT G-13



August 12, 2004

Sharon M. Davis  
Consumer Safety Officer  
Inspection and Compliance Branch  
FDA/DCRH/OCER/DMQRP  
1350 Piccard Drive (HFZ - 240)  
Rockville, MD 20850

Subject: Frederick Imaging Center - MAP ID# 15568/FDA ID# 231860,

Dear Sharon:

Enclosed are the following requested documents:

1. Entry Application for a "new" facility (7/22/04) – ACR staff noted that the facility was at the same address as a previously accredited facility with the same unit and technologist. ACR advised the facility that they would need to reinstate under the old MAP ID#.
2. Reinstatement Application with corrective action for failed test.
3. Although we have no documentation showing that Dr. Korangy purchased this facility from another owner, I've enclosed documentation showing Dr. Korangy as the current owner (see Survey Agreement in 1) and closure documentation from the previous owner.

Please let me know if you have any further questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Priscilla F. Butler'.

Priscilla F. Butler, M.S., FAAPM, FACR  
Senior Director, Breast Imaging Accreditation Programs

Enclosure

cc: Pamela Platt  
Marion Boston  
Diane Zawacki  
Vickie Jernigan  
Charles A. Finder, M.D.  
Michael P. Divine

**COPY****COPY**

MAP ID No.

15568

**PRIVILEGED and CONFIDENTIAL - PEER REVIEW**

Code of Virginia 8.01-851.17

**American College of Radiology**

1891 Preston White Drive, Reston, VA 20191-4397

**Mammography Accreditation Program  
Entry Application - Page 1**

1. Facility name: (maximum of 60 characters; this name will appear on both your ACR and MQSA certificates and on all correspondence)

FRIEDERICK IMAGING CENTERS

Street address:  
(physical location of facility)46B Thomas Johnson Drive  
Suite 100

City/Town:

Frederick,

State/Province:

MD

ZIP: 21703

Mailing address (if different from above):

Street address:

City/Town:

State/Province:

ZIP:

Telephone (appointments):

(301) 696-1410

Ext.:

Fax: (301) 696-1408

Facility owner:

Amile Korangy MD

BIN (8 digits):

52-1312-2526

Facility president or CEO:

Korangy

Amile

Contact person:

Fuller

Mona

R

Degree  
R.T.(R)(M)  
Degree

Contact telephone:

(301) 696-1410

Ext.:

E-mail address:

2. Mammography accrediting body (AB) previously used:

☒ N/A, this facility has never applied for before.☐ ACR

MAP ID No.:

MQSA ID No.:

MQSA Expiration Date:

☐ State AB

State ID No.:

MQSA ID No.:

MQSA Expiration Date:

3. Does your radiology group have other mammography facilities accredited by the ACR? check one

☐ 1 No☒ 2 Yes, specify below:

Facility Name	MAP ID No.
Baltimore Imaging Ctr. - Meidenchoice	06468-03
Baltimore Imaging Ctr. - York	15406-01
Baltimore Imaging Ctr. - Old Court	00878-01

Facility Name	MAP ID No.

4. Is this facility accredited by the ACR for other imaging modalities? check one

☒ 1 No☐ 2 Yes☐ Stereotactic Breast Biopsy SBBAP ID No.:☐ Magnetic Resonance Imaging MRAP ID No.:☐ Computed Tomography CTAP ID No.:☐ Breast Ultrasound

BUAP ID No.:

☐ Nuclear Medicine

NMAP ID No.:

☐ Radiography/Fluoroscopy RFAP ID No.:☐ Ultrasound

UAP ID No.:

5. Supervising radiologist (lead interpreting physician):

Dr. Amile Korangy

6. Has the supervising radiologist previously been an interpreting physician at an accredited facility?

☒ Yes, accreditation was granted to MAP ID No.:

All of the above named facilities

06468-03  
15406-01  
00878-01☐ No, applied but accreditation has not yet been granted to MAP ID No.:☐ No, first application by this physician.

7. Does this facility accept self-referred patients?

☐ 1 No☒ 2 Yes

8. Indicate the number of mammograms performed in the prior 12 months: Total #

0

# Screening

# Diagnostic

# Undifferentiated

If open less than 12 months, 1 month open 3 wks.

In order to apply, you must meet all the requirements specified in FDA's Quality Mammography Standards: Final Rule (April 26, 1992) (See Instruction Sheet for questions 9-12)

9. Does each interpreting physician meet the FDA personnel requirements?

☐ 1 No☒ 2 Yes

10. Does each radiologic technologist meet the FDA personnel requirements?

☐ 1 No☒ 2 Yes

11. Does each medical physicist meet the FDA personnel requirements?

☐ 1 No☒ 2 Yes

12. Do you have a QC program (equipment) and QA program (medical outcomes audit) that complies with the FDA rules?

☐ 1 No☒ 2 Yes

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MAP ID No.

15568**PRIVILEGED and CONFIDENTIAL • PEER REVIEW**

Code of Virginia 8.01-581.17

American College of Radiology  
1891 Preston White Drive, Reston, VA 20191-4397Mammography Accreditation Program  
Entry Application - Page 2Facility name: Frederick Imaging CentersHow many mammography units are there at this location? enter a number 1

Make copies of page 2 for additional mammography units.

Describe the mammography unit(s) at this site.

Unit Room #: 1Unit #: 1Manufacturer (see code table below): S L E C If manufacturer code is not available, specify manufacturer: \_\_\_\_\_Model Name: Mammomat Nova 3000 Unit Serial Number (check with service engineer if unsure): 10013 (see Manufactured: 2003 <sup>7/2</sup>Type of recording system(s) used with this unit: ☒ Screen-film ☐ Full-field digital mammography unit ☐ Computed radiography (CR) image plate ☐ XeroxDoes this unit meet equipment requirements described in FDA's Quality Mammography Standards; Final Rules (effective 4/28/99)? ☐ No ☒ YesDate that the unit's most recent medical physicist survey or a new unit's Equipment Evaluation was completed: (all items must pass) 07 / 23 / 2004  
m / day / year

**NEW UNITS ONLY:** Submit the results of your medical physicist's Equipment Evaluation (that was performed no earlier than 8 months before the date on this application) before using this new unit to examine patients. All deficient items must be corrected. To summarize the results, your medical physicist must complete the MQSA Requirements for Mammography Equipment checklist and the Medical Physicist's Mammography QC Test Summary form provided in his package.

Does this unit move from the primary site to other sites (mobile)?

☒ 1 No☐ 2 Yes \*call the ACR for specific mobile accreditation instructions

Is this a new unit that has not undergone accreditation at this location?

☒ 1 No☒ 2 Yes 7/2/04

Has this new unit moved here from a sister site?

☒ 1 No☐ 2 Yes, MAP ID# \_\_\_\_\_

Did this new unit replace an older one? (if yes, please complete below and sign)

☒ 1 No☐ 2 Yes

Manufacturer: \_\_\_\_\_ Model: \_\_\_\_\_ Serial #: \_\_\_\_\_ Year: \_\_\_\_\_

MAP Unit #: \_\_\_\_\_ Date Removed From Service: \_\_\_\_\_

Signature: \_\_\_\_\_ Print Name: \_\_\_\_\_

## Mammography Unit Manufacturer Codes

BEXR - Bennett	GEMB - General Electric	INRU - Instrumentarium	PICO - Picker	TRE - Trex Medical
CGRM - CGR Thompson	GEND - Genex-Del	LRAD - Lorad	PLAN - Planmed	OTR - Other (and specify)
DELM - Del Med Systems	GENX - General X-Ray	MOTI - Moli	SIED - Siemens	
HGPC - Fischer	IMSG - IMS	PHMS - Philips	SORX - Sorotec	

After completing the form, consult the enclosed remittance worksheet, calculate your fee, and complete the following. Payment must accompany the application.

The application fee is \$ 1325 ☐ Check enclosed payable to ACR (include MAP ID # on check) ☐ OR ☒ Charge credit cardCard No. 5490-9950-9025-2492 Exp. Date 03/05 ☐ VISA ☒ MasterCard ☐ American ExpressName of Cardholder: AMILE A. KORANY Signature: A. Korany

Mail your completed application to:

MAMMOGRAPHY ACCREDITATION PROGRAM  
AMERICAN COLLEGE OF RADIOLOGY  
1891 PRESTON WHITE DRIVE  
RESTON, VA 20191-4397

OR

For credit-card applications, FAX to:

(703) 648-9176

(Do not mail and fax the same application)

MAP 15568

**COPY**

MAP ID No. \_\_\_\_\_

**PRIVILEGED and CONFIDENTIAL - PEER REVIEW**  
Code of Virginia 8.01-581.17

*This Mammography Accreditation Survey Agreement must be signed by the facility's supervising radiologist (lead interpreting physician) and the Facility President/CEO or other legally constituted representative of the facility. Signatures may be original or faxed. Stamps, electronic, or photocopied signatures are unacceptable. The Food and Drug Administration requires accreditation of facilities providing mammography services prior to full certification.*



**American College of Radiology  
Mammography Accreditation Program  
1891 Preston White Drive  
Reston, VA 20191**

## MAMMOGRAPHY ACCREDITATION SURVEY AGREEMENT

The undersigned hereby request a survey of the quality of mammography service being performed at the location listed below. The purpose of this request is to apply for mammography accreditation at the listed location.

Facility Name and Address: Frederick Imaging Centers  
4608 Thomas Johnson Drive  
Suite 100  
Frederick, Maryland 21702

The American College of Radiology will render an objective review in regard to the findings and in regard to whether or not the mammography equipment should be accredited by the American College of Radiology.

As a condition of receiving the requested survey the Supervising Radiologist (Lead Interpreting Physician) and Facility Representative agree to:

1. Submit with the survey application the non-refundable fee for an accreditation survey, which is based upon the number of individual mammography units to be reviewed.
2. Obtain the designated mammographic detail phantom meeting the criteria specified by the ACR Committee on Mammography Accreditation and, if appropriate, remit the fee for the phantom directly to the manufacturer.
3. Provide, in a timely manner, all materials, including clinical images, phantom images, dosimeter and QC data or any other information necessary to evaluate the mammography services for accreditation purposes.
4. Receive the written final report and any peer review information by the supervising radiologist (lead interpreting physician).
5. Ensure that quality assurance and all other accreditation criteria are met and continue to be complied with during the accreditation period.
6. Perform review of mammography practice on-site by the off-site supervising radiologist (lead interpreting physician) at least quarterly, consistent with the "Off-Site Radiologist" paragraph in the document entitled Mammography Accreditation Program Overview.
7. Submit requested personnel, equipment and QC data to the ACR during the annual update.
8. Upon timely notice, and if requested by the ACR, submit to a pre-accreditation and/or post-accreditation on-site visit conducted by a survey team designated by the ACR. In connection with the on-site survey, provide all documentation, including but not limited to QC logs, images, records, or any necessary information requested by the survey team and cooperate with the survey team.
9. Provide immediate written notice of a change in the supervising radiologist (lead interpreting physician) or the mammography unit to the ACR.

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- Boulevard R/S 1/03



46 B Thomas Johnson Drive  
Lower Level Lobby Entrance  
Frederick, MD 21702  
301/846-9909 • phone  
301/846-0709 • fax

**COPY**

Mammography Accreditation Program  
American College of Radiology  
1891 Preston White Drive  
Reston, VA 20191-4397

May 10, 2004

**Regarding: Closing of facility ID number 231860**

To Whom It May Concern:

This letter is to inform you that Frederick Radiology & PET Center, LLC has ceased operations. (Facility ID 231860, MAP ID 15568-01). The Siemens Mammography 3000 NOVA 2003 is currently on site, but has been internally disconnected by the manufacturer. Frederick Radiology & PET Center vacated 46B Thomas Johnson Dr., Lower Level, Frederick, MD 21702 by April 30, 2004.

We are in the process of contacting all patients by letter to inform them of details regarding how to obtain their medical records. Please be assured, we are making every effort to contact each patient, and to do whatever is necessary to place the mammograms in the hands of the patients.

Please feel free to contact me if there are any questions or further instructions as to our obligations. I can be reached at my home office, 301.855.3768 or cell, 301.980.5393.

Sincerely,

Laura A. Reidy



9346 Baker St  
Owings, MD 20736

**CERTIFIED MAIL**



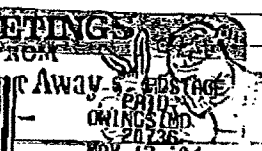
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Mammography Accreditation Program  
American College of Radiology  
1601 Preston White Drive  
Reston, VA 20191-4397

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## FACILITY CLOSURE MEMORANDUM

 PRIVILEGED AND CONFIDENTIAL • INTERNAL REVIEW  
 Code 0 VU: 001-001.17

DATE:

5/18/04

TO:

 Dr. Luther Wells  
 Frederick Radiology and PET Center  
 46 B Thomas Johnson Drive  
 Frederick, MD 21702

MAP:15568 (521)

FROM:

 Priscilla F. Butler, MS  
 Senior Director, Breast Imaging Accreditation Programs

SUBJECT:

Mammography Facility Closure - Verification Request

The American College of Radiology Mammography Accreditation Program has been notified that your facility may no longer be performing mammography. If your facility has permanently ceased performing mammography, please check the appropriate box, sign below and return this letter to the ACR within 10 business days. *This letter must be signed by either the facility's supervising radiologist or president/CEO.* Please fax the letter to Ms. Pamela Platt at (703) 648-9176 or send it to the address below. You must also remove the light blue ACR Mammography Accreditation certificate from public display at your facility. Also note that the FDA requires that you arrange for the transfer of each patient's mammography films and reports as described in their attached Guidance on Record Keeping.

If your facility is currently performing mammography (or has temporarily ceased mammography and is intending to resume within the near future), please call Ms. Platt at (800) 227-6440, x-4195 as soon as possible (but within 10 business days) to notify us of your facility's intentions. If we do not hear from you, this notice will serve as written confirmation that your facility has withdrawn from the ACR Mammography Accreditation Program and we will notify the FDA of your closure.

Finally, please note that as long as your facility is MQSA-certified, it is subject to FDA/MQSA inspection.

☒ This facility has permanently ceased performing mammography effective: 4/30/2004

Jack J. Hong, M.D. Supervising Radiologist ☒ Facility President/CEO

[Signature] (circle one)

5/18/04 date signed

Reason: ☒ Patient moved to sister site ☐ bankruptcy ☒ financial ☐ staffing problems ☐ other

Important: Please provide the name and phone number of a person that your patients may contact for instructions on retrieving their original mammography films and reports.

Bowie PET Scan - Mrs. Judith Brinkley (301) 809-1909

[Signature] print name phone number

 Facility accredited in and also permanently ceasing: ☐ Stereotactic Breast Biopsy ☐ Breast Ultrasound

Where to return completed and signed Facility Closure Form:

Revised 10/96